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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,443	07/02/2003	Andrew Lawrence Darrow	ORT-1644CIP	8116

27777 7590 11/30/2005  
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EXAMINER

SWOPE, SHERIDAN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/617,443

Applicant(s)

DARROW ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 4-7 is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response, on October 11, 2005 to the First Action on the Merits of this case mailed July 14, 2005, is acknowledged. It is acknowledged that applicants have amended Claims 1-3. It is acknowledged that applicants have renumber the second Claim 18 and Claims 19-20 to Claims 19-21, respectively, as per the Examiner's note of the prior action. Claims 1-21 are pending. Claims 8-21 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-7 are hereby reconsidered.

#### ***Specification-Objections***

Objection to the specification, because the first sentence should be updated to state that US application 10/189, 099 is abandoned, is maintained.

The specification is objected to because the amendment to page 1, within Applicants' instant response (pg 2), adds a second copy of the information found in the first two sentences of the original specification.

#### ***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **Enablement**

Rejection of Claims 1-3 under 35 U.S.C. 112, first paragraph, for lack of enablement, for the reasons described in the prior action, is maintained. In support of their request that said

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rejection be withdrawn, Applicants merely state that the claims have been amended to obviate the basis for the rejection. Said statement is not found to be persuasive for the following reasons.

It is acknowledged that Claims 1-3 has been amended. However, as amended, Claim 1 is so broad as to encompass any isolated nucleic acid molecule comprising a sequence encoding residues 1-9 of SEQ ID NO: 2. Claim 2 is so broad as to encompass any isolated nucleic acid molecule comprising at least 30 contiguous residues of nucleotides 1-1038 of SEQ ID NO: 1, wherein nucleotides 1-1010 are non-coding sequence. Claim 3 is so broad as to encompass any isolated nucleic acid molecule having at least 95% identity with nucleotides 1-1038 of SEQ ID NO: 1, wherein nucleotides 1-1010 are non-coding sequence. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claim.

While methods for testing nucleic acid molecules for use as hybridization probes and primers are known, it is not routine in the art to screen the essentially unlimited number of polynucleotides, comprising essentially any sequence, as recited. Likewise, methods for testing the polypeptides encoded by the recited nucleic acid molecules for use as antigens in the generation of antibodies or for use as proteases are known in the art, but it is not routine in the art to screen the essentially unlimited number of encoded polypeptides, comprising essentially any sequence, for such uses.

The specification does not support the broad scope of Claims 1-3 because the specification does not establish: (A) a use for all recited nucleic acid molecules; (B) which recited nucleic acid molecules can be used for hybridization probes or primers; (C) which nucleic acid molecules encode polypeptides that can be used for generating specific antibodies; (D)

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which nucleic acid molecules encode polypeptides having protease activity; (E) regions of the nucleic acid or protein structure which may be modified without effecting the desired activity; (F) the general tolerance of the desired activity to modification and extent of such tolerance; (G) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired function; and (H) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of nucleic acid molecules with an enormous number of modifications of the polynucleotide of SEQ ID NO: 1 (which encodes SEQ ID NO: 2), wherein the nucleic acid molecule encodes a protein with any function or no function. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

For these reasons and those provided in the prior action, rejection of Claims 1-3 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained.

#### **Written Description**

Rejection of Claims 1-3 under 35 U.S.C. 112, first paragraph, for insufficient written description, as described in the prior action, is maintained. In support of their request that said

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rejection be withdrawn, Applicants merely state that the claims have been amended to obviate the basis for the rejection. Said statement is not found to be persuasive for the following reasons.

It is acknowledged that Claims 1-3 has been amended. However, the amended claims are directed to a genus of nucleic acid molecules (i) comprising a nucleotide sequence capable of encoding residues 1-9 of SEQ ID NO: 2, (ii) comprising at least 30 contiguous nucleotides of residues 1-1038 of SEQ ID NO: 1, wherein nucleotides 1-1010 are non-coding sequence, or (iii) having at least 95% identity with residues 1-1038 of SEQ ID NO: 1, wherein nucleotides 1-1010 are non-coding sequence.

The specification does not contain any disclosure of the structure and/or function of all said nucleic acid molecules. The genus of polynucleotides that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding many different proteins or no protein sequence. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses the structure and function of only a single species of the claimed genus, as set forth by SEQ ID NO: 1, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Allowable Subject Matter***

Claims 4-7 are allowable.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

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**SHERIDAN SWOPE, Ph.D.**  
**PATENT EXAMINER**